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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,663	06/27/2001	Todd A. Hall	7883.0005-04	5780

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

DAVIS, DANIEL J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 06/19/2003 - 9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/891,663

Applicant(s)

HALL ET AL.

Examiner

D Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 69-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The anchoring member is disclosed in Fig. 11 is not concentric with the lumen of the elongate tubular body.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69-74, 76-79, 81-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Maki et al. (US 6,261,260). Maki disclose a delivery catheter (Fig. 11) comprising an elongate tubular body 3, a proximal anchoring member 2, and a distal steering member 2. Maki disclose the use of one balloon that is used to steer the catheter tip. The Maki device is a balloon with areas of greater and lesser inflatability, which steer the catheter. The inflatable balloon may be divided into two equal parts each having an area of greater inflatability. The result is a proximal anchoring member and a distal steering member. The two members push against opposite sides of the vessel wall to steer the catheter tip. Although the balloon is cylindrical, the anchoring member and the steering member are mounted on opposite sides of the tubular body. The tubular body is formed of a flexible polymer (Col. 9, lines 21-27).

Claims 69-78 and 81-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Grinfeld et al. (US 5,312,344). Grinfeld disclose a deliver catheter (Fig. 2) comprising a tubular body 6, an anchoring member 10, and a steering member 9. As illustrated, the steering member 9 acts to change direction of the distal tip. The role as steering member is accentuated considering that as the catheter is pushed distally while the balloons are in the inflated state, the steering member acts to redirect and steer the catheter as it moves through the ascending aorta. Since the steering member and the anchoring member both contact the vessel wall throughout an entire radial 360 degrees, the two members do engage oppositely located vessel wall portions. Likewise, the members are mounted on opposite sides of the tubular member, even though they also have some sides in common.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(c) which forms the basis for all obviousness rejections set forth in this Office action:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 94-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maki in view of Wilk (US 5,429,144). Maki disclose a steerable balloon catheter tube but fail to disclose a method of advancing a medical device/stent through the lumen of the deliver catheter and out the distal end. Nevertheless, Wilk discloses a method of advancing a stent through a steerable catheter at an angle with the coronary vessel wall and implanting it in a myocardial wall as a means for deploying a stent (Col. 9, lines 1-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Makis' steerable balloon catheter as taught by Wilk to implant a stent in the myocondrial wall between the coronary vessel and a chamber of the heart.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD  
June 13, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700